DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95152d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

Certified Mail
Return Receipt Requested

WARNING LETTER

FLA-05-11

November 22, 2004

Yasuhiro Hayashi, President
Miracle Fish, Inc.
500 NE 185th Street
Bay #12
Miami, Florida 33179

Dear Mr. Hayashi:

On August 25-26, 2004, the United States Food and Drug Administration (FDA) conducted an inspection of your facility located at the above address. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

During our inspection, the FDA Investigator observed deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulations and provided your Vice President/HACCP Manager, Laura L. Taylor, with a copy of the Form FDA 483 (copy enclosed), which presents the Investigator's evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm has a product specification for tuna and escolar imported from Ecuador that does not adequately address the food safety hazard of histamine that is reasonably likely to be presented by these products.

2. You must implement affirmative steps which ensure that the fish and fishery product you import are processed accordance with the Seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, you firm did not perform an affirmative step for wahoo manufactured by [redacted] in Ecuador.

FDA notified you of these same deviations in a letter dated September 23, 1998 (enclosed). We acknowledge receipt of Mrs. Taylor's written response dated September 24, 2004, to the most recent Form FDA 483. We have reviewed this response and have made it part of the official file. The response is inadequate because it did not include supporting documentation addressing the deficiencies listed on the Form FDA 483 and therefore, we are unable to evaluate whether corrections have been made. Additionally, we suggest that you have separate HACCP plans that identify each significant hazard for each different type of product that you import.

The above-identified deviations are not intended to be an all–inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and FDA's regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and /or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing, within 15 working days from your receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Virginia L. Meeks, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida,- 32571. If you have questions regarding any issue in this letter, please contact Ms. Meeks at (407) 475-4731. We look forward to working with you to achieve a successful HACCP program.

Sincerely,

Emma R. Singleton
Director, Florida District